



APR 19 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Teri Juckett
Regulatory Affairs Manager
ANGIODYNAMICS®
603 Queensbury Avenue
QUEENSBURY NY 12804

Re: K040402

Trade/Device Name: AngioDynamics, Inc. More-Flow™ Hemodialysis Catheter and
Procedure Kit

Regulation Number: 21 CFR §876.5540

Regulation Name: Blood access device and accessories

Regulatory Class: III

Product Code: 78 MSD

Dated: February 11, 2004

Received: February 17, 2004

Dear Ms. Juckett:

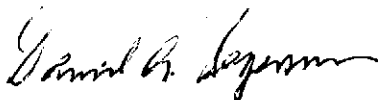
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,


for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE**510(k) Application:** New Application

K040402

Device Name:

AngioDynamics, Inc. More-Flow™ Hemodialysis Catheter and Procedure Kit

Indications for Use:

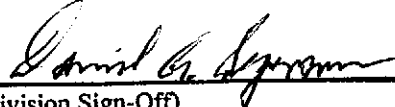
The AngioDynamics, Inc. More-Flow™ Hemodialysis Catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis.

It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient.

Alternative insertion sites include the subclavian vein as required.

Catheters greater than 40cm are intended for femoral vein insertion.

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Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

K040402

Prescription Use ☒
(Per 21 CFR 801.109)**OR****Over-the-Counter Use** ☐